HOUSE OF LORDS SESSION 2001–02

MINUTES OF EVIDENCE
TAKEN BEFORE

THE SELECT COMMITTEE ON ANIMALS IN SCIENTIFIC PROCEDURES

Tuesday 1 May 2001

ANIMAL PROCEDURES COMMITTEE

The Reverend Professor Michael Banner, Dr Maggy Jennings, Professor Iain Purchase and Mr Richard West

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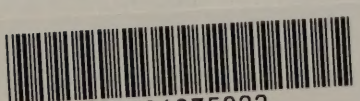

MINUTES OF EVIDENCE

TAKEN BEFORE THE SELECT COMMITTEE ON ANIMALS IN SCIENTIFIC PROCEDURES

TUESDAY 1 MAY 2001

Present

Brennan, L.
Hunt of Chesterton, L.
Lucas, L.
Nicol, B.
Onslow, E.
Richardson of Calow, L.
Smith of Clifton, L. (Chairman)
Soulsby of Swaffham Prior, L.
Warnock, B.

Memorandum by the Animal Procedures Committee

OVERVIEW

A note by the Chairman of the Animal Procedures Committee, prepared in April 2001 for the House of Lords Committee on Animals in Scientific Procedures

1. During the year 2000 the Committee made significant progress on the agenda which emerged from our review of the Act, completed in 1998. We concluded consultation exercises on openness and biotechnology. Using the results of those exercises, two working groups of the Committee worked hard at analysing the difficult issues involved and formulating practical recommendations. That work enabled us to offer our considered advice on openness to the Home Office at the end of the year, and our report on biotechnology is also close to finalisation. We also started a wide-ranging consultation exercise about the cost-benefit assessment, and made encouraging progress on other areas of our review of the Act. The APC Secretariat's note on events and progress in 2000 includes a work programme for the coming year, which gives details of how we intend to take these and other issues forward[1].

2. The Committee also carried on with its regular duties. For example, our Research and Alternatives sub-committee continued to identify suitable projects for funding to identify practical alternatives to the use of animals. The Committee also gave advice on certain applications, such as those involving microsurgery training using animals.

3. The Committee prides itself on bringing an independent and critical scrutiny to the use of animals in scientific procedures. In pursuit of its general duties and particular enquiries it finds itself asking whether the current regulatory regime is adequate, effective and efficient in meeting the objectives of the legislation, and it is concerned to make practical proposals for improvement where appropriate.

4. Perhaps inevitably, the Committee is criticised as either complacent towards current practice or as unduly hostile. A better appreciation of the Committee's function and work would be assisted by recognition of two key points. In the first place, there is widespread misunderstanding of current practice, as recent controversies have revealed. For example, it is plainly not commonly understood that most scientific procedures do not cause grave suffering to animals, and that even the taking of a blood sample constitutes a procedure under the Act. In the second place however, even supposing a better understanding of the use of animals in scientific procedures, the Committee's programme of critical appraisal of the Act and its working is fully warranted. In no sense can it be characterised as anti science or industry. Rather, it should be recognised that the continuing investigation of the use of animals in scientific procedures by the Committee is a key element in ensuring confidence in the regulation of what is and is likely to remain a highly contentious area.

Michael Banner
Chairman

25 April 2001

[1] The substance of this document is contained within the published Report of the Animal Procedures Committee for 2000, 19 July 2001 (HC 126), The Stationery Office.

Examination of Witnesses

THE REVEREND PROFESSOR MICHAEL BANNER, Chairman, DR MAGGY JENNINGS, Member, PROFESSOR IAIN PURCHASE, Member, and MR RICHARD WEST, Secretary, The Animal Procedures Committee, examined.

Chairman

1. Good afternoon, Professor Banner and Dr Maggy Jennings and Professor Iain Purchase.

(*Reverend Professor Banner*) Professor Iain Purchase will be with us in a moment, my Lord Chairman.

2. The acoustics in this room are very, very bad, so if we can all speak up, not least for the shorthand writer. Professor Banner and colleagues, thank you very much indeed for coming to see us today. As you know, this is the first meeting of the Committee. I repeat, for Professor Purchase's benefit, we do have to speak up. Professor Banner, would you begin by introducing your colleagues and yourself?

(*Reverend Professor Banner*) Yes. I am Michael Banner, Chairman of the Animal Procedures Committee and Professor of Moral and Social Theology at King's College, London. I have with me from the committee, Dr Maggy Jennings, who is Head of the Research Animals Department at the RSPCA and, to my left, Professor Iain Purchase who was, until recently, Director of Central Toxicology for what was then Zeneca, and is currently a visiting Professor at Manchester University, and to his left is Richard West, Secretary to the Animal Procedures Committee (APC).

3. Thank you very much. If I might ask the first question. What is the principal role of the Animal Procedures Committee? How does the APC operate? What, in fact, takes up most of its time in practice?

(*Reverend Professor Banner*) We see ourselves, my Lord Chairman, as a committee, as an independent and expert body, which gives advice. We are charged under the Act with giving advice to the Secretary of State on his duties in relation to experimental animals. We can have issues referred to us by the Home Secretary, though that has been infrequent. Otherwise we undertake really, as a rolling programme, a review of the various important elements of the Act and its operation. Our major work, I would say, is in sub-committees of the main committee which look at the detailed aspects of the regulation as it relates to different issues. So, for example, we have a Standing Primates Committee, which looks at issues to do with the use of primates, and we have committees that have set up working groups which are set up to deal with particular issues. We have just had a group that has produced a report on biotechnology.

4. Thank you very much. On the third point I made, what takes up most of the time?

(*Reverend Professor Banner*) The committee meets as a full committee seven or eight times a year; that would be a day meeting. The sub-committees and working groups would meet on many more occasions, so the balance of the work is definitely in the working groups and sub-committees. I would say that most of our time, although we deal with applications, for example, which are referred to us for particular consideration and so on, is taken up with the rather more strategic long-term consideration of the effectiveness and adequacy of the present regulations and regime.

Chairman: Thank you.

Baroness Nicol

5. These are licence applications that you are referring to?

(*Reverend Professor Banner*) Under the Act in practice it has been established by the Home Office that particular applications of a sensitive nature are referred to the committee for advice. For example, applications to do with the use of primates in procedures of substantial severity. Recently an application was referred to us which involved the use of tobacco smoke as a causative agent in creating a model for the study of disease. So the Home Secretary, by convention and in particular cases, may refer particular applications to us for further advice although, of course, the Home Secretary will have had advice from both the Animals, Byelaws and Coroners Unit and the Animals (Scientific Procedures) Inspectorate.

Lord Lucas

6. Can I ask who sets that framework and which references are made to determine this, what rules? Who decides in practice whether something gets to you?

(*Reverend Professor Banner*) I would need to check whether it is a matter of the statute or whether of convention. I think it is a matter of convention that particular applications, for example applications to do with microsurgery, by convention have been referred to the Committee. I would need to make a note on that and check that with my Secretary. Applications involving procedures involving primates, wild caught primates, for example, are referred to the committee. I forget whether that is by statute or whether by convention.

Chairman

7. I am advised that it is statute. Perhaps you would write to us and clear that up after the meeting.

(*Reverend Professor Banner*) Yes, we could certainly, my Lord Chairman. I think the point to make would be whether it is by statute or convention is probably in one sense not of great interest to me or the committee in the sense that if the committee took the view that it would be worthwhile for more applications to be referred to us, we would not be reticent in asking the Home Secretary to do that. The Home Secretary would of course be entitled to say no, but if the committee considered that there would be merit in our seeing more applications then we would take the initiative on that.

Earl of Onslow

8. May I ask from what source do you derive your moral authority for asking questions? From what source and on what basis does that moral authority come and how do you arrive at it?

(*Reverend Professor Banner*) I would say, my Lord, that we operate within the terms that are laid down by the Act.

9. That is not the question I asked. The question I asked was the moral authority rather than the statutory authority.

(*Reverend Professor Banner*) The moral authority of the committee?

10. No, the moral authority of the ideas upon which you give approval or disapproval?

(*Reverend Professor Banner*) I am afraid I have to repeat my answer that we—

11. Moral authority does not come from statute, it comes from something higher than statute. What is the higher authority for your opinions?

(*Reverend Professor Banner*) I have to say that we think our authority comes from the statutory authority we are given by the Act. I would say that members are scrupulous in considering applications, for example, in the terms that are required by the Act and not according to their own particular points of view. So we have members of the committee who are, personally speaking, absolutely and fundamentally opposed to all vivisection who, nonetheless, will support an application if they take the view that the application falls squarely within the terms provided by the Act. I am not trying to be difficult but that is what I understand to be the nature of the operation of the committee.

Chairman

12. If you have any further reflections on that conundrum perhaps you will write to us as well. My second question is what is the relationship between the APC, the Animals, Byelaws and Coroners Unit (ABCU) in the Home office, and the Animals Inspectorate? To what extent does the APC liaise with different Government departments as it goes about its operations?

(*Reverend Professor Banner*) The APC as I said, my Lord Chairman, offers independent advice to the Home Secretary. The Animals, Bylaws and Coroners Unit is responsible for the policy on the regulation and use of animals and provides advice directly to the Secretary of State independently. The Animals (Scientific Procedures) Inspectorate is part of the Home Office and inspectors are responsible for advising the animal procedures section of ABCU in relation to individual licence applications and in relation to compliance. So we are three separate parts of the whole, if I can put it like that, although the APC is an independent committee, of course, and not part of Government machinery. We liaise with other bodies regularly, for example with the Farm Animal Welfare Council (FAWC) and the Agriculture and Environment Biotechnology Commission (AEBC). With other Government departments such liaison would be a matter in the first instance of us advising the Home Secretary that such liaison was appropriate, but we would not regard it as our task in the first instance to liaise.

13. All of these things that appear to be radial are often circumferential. You do not have informal chats amongst yourselves?

(*Reverend Professor Banner*) We may well have informal chats and at meetings of the committee officials from ABCU and the Inspectorate are present by invitation, so there is informal advice. We regard it as very important because of the expertise and knowledge which the Inspectorate, in particular, has about the operation of the Act on the ground.

14. So these do not operate as entirely hermetically sealed individual units?

(*Reverend Professor Banner*) No, absolutely not.

15. My third question is what notice do you take of regulatory systems abroad? How does the regulatory system and practice in the UK compare with systems elsewhere? How do standards of animal welfare in the UK compare with those elsewhere? I think perhaps these are all rather broad questions and they subsume a number of sub-sets. Could you perhaps leave the standards abroad as a separate one. In what sense do you take a comparative perspective internationally of what is going on?

(*Reverend Professor Banner*) We would not in the first instance regard that as a prime responsibility. Our function under the Act is to advise the Secretary of State on his functions and duties under the Act. As you will know, my Lord Chairman, the Act, the A(SP)A, is an implementation of a European Directive[1] and, although the Directive will be implemented in different ways in different countries, it would be true to say that to some extent the fact that there is an implementation of a Directive ensures some uniformity. Level playing field would be putting it too strongly, but one would expect there to be similar regimes, although there are significant differences, and it could be said that the Act is more stringent than the Directive in a number of respects. In terms of how we take account of it, I would have to say that we have members from welfare bodies, members of the committee who are themselves licence holders, experienced people from industry and so on, who do indeed have some knowledge of different regulatory regimes and how they operate and where that is relevant to our deliberations we would turn to them for advice.

16. While I appreciate that it might not be your prime responsibility, nevertheless do your deliberations give you some feel for the standards of UK animal welfare in comparison, say, with our European partners?

(*Reverend Professor Banner*) I could ask my colleagues to comment on it. I have to say that our feeling as a committee is that there is a good deal of anecdote on that subject which says either the regulations are not as good, or that they are as good, or that there is as good welfare but fewer regulations in some countries and in some countries more regulations and less good welfare. I think it is a very difficult matter on which to establish evidence. For example, one matter which is of crucial importance, I would suggest, is the number of inspectors engaged under any regime in ensuring compliance. So it may

[1] European Directive 86/609/EEC.

Chairman *contd.*]

well be that a country has very similar regulations in the black letter law, but on the ground it can be very different just because there is no reasonable expectation that there will be a surprise visit by an inspector. I know that my colleague, Professor Purchase, is chairing an Expert Group on Regulation which is trying to provide some hard evidence. This is not a part of our committee's work but the committee will take notice of this. If you would like, my colleague, Professor Purchase, could comment in more detail.

(*Professor Purchase*) Thank you. I would reinforce what Professor Banner has said, that there is a lot of anecdote around. One speaks to people who have worked in more than one country and they provide their opinions on that. It is possible to study the regulations in quite a lot of detail, and some of us have done that although not within the context of the Animal Procedures Committee, so my comments are not deliberations of the committee. You can see that there are substantial differences, particularly if you go to the US and France, in comparison to what goes on in the UK. What is much more difficult to establish is what impact that has on animal welfare. I would have to say that there is one, if you like, independent scientific control or impact on animal welfare, and that is that many of the scientific journals which publish results of work carried out using animals have a code of ethics, or a code of animal welfare, and the papers are then deliberately refereed with respect to that code before they are published. I know from personal experiences that journals I have been involved in have rejected papers because they were considered to be poor in terms of ethical standards.

17. Therefore, if only the ethical reports surface and the others are consigned to the dustbin we do not know what ratio of acceptable to unacceptable procedures there are?

(*Professor Purchase*) No. But there is an incentive if you want to advance your scientific career to have papers that are published in good journals. That would be the driver that would affect it.

Earl of Onslow

18. May I ask is there a different interpretation of the meaning of animal welfare in England, in France, in the United States? Let us leave aside the United States, let us concentrate solely on Europe. Is there a different meaning applying to animal welfare in different parts of the continent? How would you define it?

(*Professor Purchase*) I am afraid I cannot comment on your first question in regard to whether there is a different meaning in different countries. One might imagine because of the different cultural environments that there would be differences. Certainly my observation in visiting laboratories in different parts of the world is where the laboratories are located in agricultural environments they have a different perception about animal welfare than where they are located in advanced Western cities. So there is certainly a difference there. How do I define animal welfare? I think probably Dr Jennings is really the expert at defining it. I think what we are looking for is the ability of the animal to express its normal behaviour patterns in so far as it is possible when it is kept under experimental conditions.

(*Dr Jennings*) I think there is a difference in the way that animal welfare is perceived. We have found—and I will use the United States as an example here because this is where we found it particularly evident—that people confuse the issue of animal health, and having an animal that is in good physical health, with an animal that has good welfare where you are talking about satisfying its behaviourial, sociological and psychological requirements. I do not think that difference of opinion is just within the States and the UK, I suspect that you will also get that division within Europe. We (the RSPCA) have not visited many laboratories in Europe. In fact, we have probably only been to three. In all of those laboratories the standards have been lower than in the UK. There is a lot of anecdotal evidence, I would entirely agree with my colleagues. But I am very much involved with the training of prospective licensees in the UK and you do get people coming on to licensee training courses from countries in Europe and their attitudes to animals and their welfare, to laboratory animal use in general, and their understanding of the principles of laboratory animal welfare can, in fact, be very different from the understanding of UK licensees. I think that this contributes to the anecdotal evidence that there are differences in standards between the UK and other countries.

Baroness Nicol

19. Are the differences obvious enough and sharp enough to make a commercial difference? Have you come across any evidence that research is lost to this country because there is a difference; or gained?

(*Reverend Professor Banner*) I am a lay person and I have visited different laboratories in this country and the difference between the best facilities for certain animals and the less good facilities is marked to the naked eye of a lay person and one supposes that must have cost implications. However, I think it is extremely difficult to find firm evidence that research has been lost because of higher standards, although it is often claimed. The difficulty with establishing it as a firm piece of evidence is there are so many compounding factors, as it were, as to why research might be placed either here or somewhere else. It is difficult to isolate one factor. It is often said, I think, by some laboratories that the fact that we have good welfare in certain areas ensures the reliability and trustworthiness of many of the tests, and that is an important consideration. I am not in a position, as a non-scientist, to judge that but that is often said by laboratories. Would you like to comment on that particular point?

(*Professor Purchase*) I do not have anything more to add.

Earl of Onslow

20. Can I come back to Dr Jennings' remarks. She said there was a difference between the health of an animal and its sociological wellbeing. She also said

Earl of Onslow *contd.*]

there were differences in the principles of animal welfare in different parts of the world. First of all, I will use the anecdote of a racehorse. There is no way if you stick a racehorse in a box and it has to run three, three and a half miles at Epsom, an immature horse with a crippled jockey on top of it, that that is in tune with the sociological habits of wild horses. I find this concept quite difficult to differentiate between sociological welfare and the health of the animal. Secondly, you say that the principles of animal welfare are different in country A to country B, but how do we know that our principles are superior to those of somebody else?

(*Reverend Professor Banner*) Can I just help my colleague by giving a lay person's example which I found very striking on visiting a laboratory last year. We were shown rats caged, singly or in twos. If you drop a piece of food into a cage with two rats—it was not done—I am assured that they would almost kill one another. On the other hand, if you put 30 rats in a large case you can drop a piece of food in—they will have established a social system—and the dominant rat will take the food, there will be no squabble about it, and to the lay person they are much easier to handle and so on. I think that is the sort of social needs difference that good laboratory practice is sensitive to. To a lay person that was a very striking example.

21. I remember my father saying that about rat catchers, that if you put a terrier in a corn bin and if there were lots of them they would all run into the corner until there were only two left and then there would be a punch-up. I am trying to get to the root of this whole moral question as to what questions we are asking. It is not an easy question, I do not think, that is why I am picking up on what could be regarded as esoteric questions. I am still not happy because I do not understand the answer and, frankly, I do not know what the answer is myself.

(*Reverend Professor Banner*) There is a distinction, I take it, to be drawn between morally how important an animal's welfare is and how one establishes welfare. About the establishment of welfare, there are detailed scientific disputes and the committee only recently, in looking at a report that will be out very shortly in relation to biotechnology, was considering the merit of certain tests of welfare and whether they really did show better welfare or not. Obviously on the establishment of whether it is poor or good welfare, some of it might be obvious, there are some fine judgments to be made which are backed by scientific reason of a persuasive or unpersuasive sort depending on your estimation of it. You are absolutely right to say that one has to be very sensitive to the question of how welfare is established and what is supposed to be good welfare is often not good welfare. What one thinks might be kind to an animal is not the same as what constitutes it.

(*Dr Jennings*) I would like to emphasise the very big difference between health, health on its own, and the overall welfare of the animal because I think that is really crucially important. Health is a part of welfare. You will not have an animal with good welfare if it is not healthy. The word "health" tends to encompass physical health but this is not the sole consideration. Another very simple example, I think, is if you look at the husbandry of rabbits in laboratories. In the past, and still in a lot of laboratories, rabbits would be kept in a cage, they would be given food and water and they would be kept clean, and their health would be fine by most of the parameters by which you would examine these animals. However, rabbits are social animals: they do not spend all their time sitting in a barren cage, they spend their life doing things. The Farm Animal Welfare Council drew out the principles of the five freedoms, one of which says that the animal should have freedom to perform most of its natural behaviours. If you give a rabbit its freedom to perform its natural behaviour, it wants to hop around and jump all over—

Earl of Onslow: We all know about rabbits!

Chairman

22. I think we should follow the illustration of more than two rats where possibly the presiding rat can allocate rations fairly.

(*Dr Jennings*) If you are going to keep animals for experimental purposes you cannot just consider health, you have to consider their overall welfare and consider their social and behaviourial needs as well.

Lord Hunt of Chesterton

23. Could I just pick up that point and go back to the first question from Lord Onslow. It seems as if you have been talking about these animal welfare issues involved in agriculture and welfare issues involved in animal experimentation, and you operate entirely within a statute associated with animal procedures. There are other statutes and Acts to do with agriculture and there are many aspects of agriculture, battery chickens and so on, that people are concerned about. Is there some connection between these two areas? Are the definitions of welfare used the same for you as when you operate for MAFF, or are we really talking about two completely different areas?

(*Reverend Professor Banner*) As you say, they are different statutory responsibilities. The Farm Animal Welfare Council has a responsibility for advising on the welfare of farm animals. The Scientific studies which have been done which relate to welfare are relevant to the work of those who are concerned with both, although of course the particularities of the experiments and studies may vary. The question of the definition of welfare came up previously. The word which is key for the committee on the legislation is cost. One of the costs to the animals may be in harm in a very obvious sense although that could be a harm to welfare. Yes, we consider it. It is not a word that we grapple with the definition of but we would be concerned with the scientific evidence for good and bad welfare.

Earl of Onslow

24. You say you do not grapple with the meaning of the word welfare—

(*Reverend Professor Banner*) The definition.

Earl of Onslow *contd.*]

25. But you then apply scientific rules to it. How can you apply scientific rules to something which you do not know the meaning of?

(*Reverend Professor Banner*) I did not say I did not know the meaning of it, my Lord, I said we did not grapple with a definition.

26. If you cannot define it ergo by its nature you do not know the meaning of it.

(*Reverend Professor Banner*) I would not say that.

27. No, you did not say it.

(*Reverend Professor Banner*) I said I would not say it.

28. What you said was "I cannot define welfare".

(*Reverend Professor Banner*) I said we do not, as a committee.

29. If you do not define it you cannot know what it means.

(*Reverend Professor Banner*) I would quibble with you, my Lord. I cannot define night and day but I know the difference between them.

30. Yes, you can. I am sorry if I am being beastly and I am sorry if I am giving you a hard time but the point is unless we get the definition of what we are talking about right at the beginning we will not get anywhere, we will start producing waffle. I do not know the answer myself, I do not understand the answer, that is why I am asking for you lot, who are cleverer people than me, to give it to me.

(*Reverend Professor Banner*) A characterisation of welfare has already been given, which is the ability of an animal to express its normal behaviour and I would add, I think, to cope with the environment in which it is placed. I would call that a characterisation, I would not call it a definition. I would say that characterisation is a working definition or characterisation which is sufficient to have a meaningful discussion.

Baroness Warnock

31. I have great sympathy with you saying that you know what it means but you cannot give a definition of it, the two things are not incompatible. Surely what is constantly in the minds of people who are trying to decide whether the welfare of the animal is being given due consideration is the negative criteria if it turns out for some inexplicable reason that the welfare is not good enough, because every species of animal expresses itself differently and, therefore, you may not know in advance what behaviour for a particular species of animal is going to show that its welfare has been overlooked, even if it is healthy. I absolutely accept that distinction. In a way one does not need a definition because one just needs criteria for judging whether the welfare is going down.

(*Reverend Professor Banner*) Typically that would be so in a licence application where one would see "end points" or less formally "indications of poor welfare" which would be a sign of a problem, for example if an animal becomes withdrawn or declines to eat or starts pulling out its fur, whatever it might be.

32. That would be a sign that the welfare was not all it should be. I tend to think that we will be wasting our time if we try to get a definition that is clear cut because it is almost a defeasible concept: the animal is okay if it is behaving as normally as it can and it is not okay if it is showing signs of distress. Would that not be right?

(*Reverend Professor Banner*) Can I ask whether my colleague, Professor Purchase, would like to comment on this because he has an interest and expertise in this.

(*Professor Purchase*) I recollect about two years ago we had a retreat for the Animal Procedures Committee and I think it was Professor Dawkins who made a presentation to us. The thrust of her presentation was right at the heart of this question and it was that we should be wary of using anthropomorphic values and imposing them on the animals and that we should actually observe the animals. In particular she gave us the example of the question about battery farming of chickens and said that chickens, because of their nature of how they live in the wild, might actually be happier in battery cages than they would be on an open floor because they were used to being in confined spaces. If that is the case you have to go and make observations to see whether an open floor is better than a battery cage, rather than saying "I, as a human being, would prefer an open floor than a battery cage". I think that maybe helps in distinguishing the two features.

Lord Lucas

33. I just want to pick up on the remarks of Professor Banner that he had seen a marked difference in standards. Who plays the role of Chief Inspector of Prisons and reports on these and makes them public?

(*Reverend Professor Banner*) Not the Animal Procedures Committee. I think that would be a matter in the first instance for the Animal Inspectorate, who are responsible for granting licences not only for projects and to individual experimenters but also to establishments, and have a responsibility for setting standards for good practice. I will just turn to my Secretary to see whether he wants to add anything. I would not suggest that standards are not being observed but rather saying the best practice is much better than the practice which I hope conforms, and I expect conforms, with the regulations and requirements. The difference between the very best practice and less good practice is quite marked to a lay person.

(*Mr West*) That was my point, there was no suggestion that those lower standards were in breach of the regulations.

Lord Soulsby of Swaffham Prior

34. I may say, my Lord Chairman, some of this discussion I have heard before about what welfare is and how you define it. Perhaps I should declare that I was a member of the APC in its first four years of existence. What are the current trends in scientific procedures involving animals? The needs for technologies have changed substantially over the last ten or 15 years. Has the work of the committee changed over that time under the Act since it has

Lord Soulsby of Swaffham Prior *contd.*]

been in force? Finally, how do you see the role of the committee changing with the vast changes in biological sciences that are taking place right now?

(*Reverend Professor Banner*) I can answer that question by saying I could not relate all of the changes in the committee and the way it operates to the biological sciences. If I could separate out those two. There have been changes in how the committee operates. The present Government has increased the committee in size and I would say, and as Chairman I am certainly happy with this, has increased the width and breadth of representation on the committee so we now have, I would say, a very wide representation of points of view on the committee. That is one change in the committee. In terms of how we operate, and I cannot comment on the early existence of the committee, I think compared with previous years to my becoming Chairman in 1998, we have become more proactive as a committee, we are taking on more issues to investigate and identify for ourselves rather than reacting to events and business that come to us. You will know that there was a review of the Act[2] and we have an agenda of investigations of various key areas which is ongoing. In terms of how our work relates to the changes in the biological sciences, I might ask my colleague, Professor Purchase, to comment. One trend up to now has been that the number of animals used has been decreasing but I think there is every expectation that will not continue and that the development of genetic modification and the possibilities that offers for experimenters will mean that the numbers increase. I am not sure I can suggest immediately how that will affect the work of the committee. I think the committee feels that it must be sensitive to developments and adapt its work as necessary in the light of those developments. I think that the perception that there will be an increase in the number of animals used is one which is shared quite widely by the scientific community.

35. You will have more specifically designed animals as a result of your ability to do genetic modification so although the number of animals may go up, the number of nondescript animals that are not, in fact, specifically designed for the work will go down, hence your results will be much more meaningful.

(*Reverend Professor Banner*) I am sure that could be argued, yes.

(*Professor Purchase*) It would be argued by some, yes.

Chairman

36. Does Professor Purchase want to say anything?

(*Professor Purchase*) Thank you, my Lord Chairman. It is interesting that the numbers have been declining over the last more than ten years. It is equally interesting that I do not know of anyone who has done a systematic study of why that has happened. I suspect that if you look at the figures, the majority of reductions have been made within industry, and I suspect what has happened is that the pharmaceutical industry has become more efficient in the way it does its experiments, relying more on modern *in vitro* genetic methods rather than using whole animals. I am sure of that. There is a problem here: it is frequently expressed that the number of animals used experimentally in some way reflects the effectiveness of the Act. I would like to say that must be far from the truth because it does not measure any output. If the number of animals increases two fold but the research output increases ten fold then we are in a better position than we were before. The factors that do influence the number of animals are the excitement of the research, the opportunity it provides, and what we are seeing now is an increase in the opportunity provided by the use of genetically modified animals. The second factor, which derives from that, is the amount of funding that is being spent in this area of research. We have seen the big funding agencies in the UK wanting to exploit the knowledge from genomics, so it follows that you would expect to see more animals used for that purpose if animals are the only means of exploiting it. Finally, it is the way in which the research is done and that comes to the use of alternatives. I believe that there is pressure on people to use alternatives, both legislative and moral pressure, and we will see that continuing. The use of alternatives will not necessarily reduce the number of animals.

(*Reverend Professor Banner*) If I could add a very quick supplement to that. It seems to me what is very important when I talk to people about this committee and its work—I should add as a rider in terms of our working the Animal Procedures Committee has adopted, along with other Non-Departmental Public Bodies, use of good practice in regards to openness and consultation and so on—is that the Act as such gives no purchase to the regulators to reduce the numbers, except in the key provision that a licence shall not be granted where an alternative is available. The Act as such does not give purchase to the regulator to reduce the number of animals as a total. That is a brief way of saying what Professor Purchase said more expertly than I can.

Earl of Onslow

37. May I ask a question on the number of animals. Presumably most animals are rats and mice, is that right?

(*Reverend Professor Banner*) The majority, my Lord, yes.

38. If you need more animal experiments you just breed more rats and mice whose sole purpose in this life, in their short and transient existence, is to be an object of experimentation. So they only come into existence because somebody wants to do something to them. Actually, the number of animal experimentations is not as relevant as if one was going, say, to capture a wild chimpanzee and do experiments on that. There does seem to me to be a very serious difference between taking monkeys out of the wild, which I know there has been some of, and actually breeding rats and mice. You put a male rat and a female rat in a cage and lo and behold in a nanosecond you will have hoards of them. There does seem to me to be a difference in this numbers

[2] Report of the Animal Procedures Committee for 1997, Annex F.

Earl of Onslow *contd.*]

game. The numbers game in itself is not really very relevant.

(*Reverend Professor Banner*) Certainly there is no mechanism in the Act for controlling or capping the numbers. Obviously in terms of the different considerations about costs, as it were—

39. I am not asking costs, I am asking a woolly moral question.

(*Reverend Professor Banner*) I meant in the wide sense, I did not mean financial. I meant costs in the sense of harms, burden to the animals.

40. Yes.

(*Reverend Professor Banner*) The question of whether they are wild-caught or bred for the purpose is relevant. I think the key question I would say—and it is not one understood by the public, it is a key issue in terms of public perception—is it is often thought, and a number of articles written at the time of the Huntingdon Life Sciences issue presuppose, that every animal involved in experiments has a short tortured life and dies in pain; that is plainly false. I think that in terms of any future increase in numbers the key consideration, it is not for me to comment on but in terms of public acceptability, would be a better understanding that an experiment can be the taking of a blood sample, for example, not the pinning of a rat to a table while it is tortured with no anaesthesia, which is I think a popular misconception about what nearly every experiment involves.

Lord Hunt of Chesterton

41. May I just ask a question of Professor Purchase. He referred to the industrial aspect of this. I thought he was going to continue by saying "the industry is now using more in vitro genetic methods". My understanding is that just as they are now building aeroplanes without testing them in a wind tunnel, or to some extent, the use of computer modelling is also a part of that business of extending the value of any kind of animal or laboratory experiment. Is that right? Could you comment upon where that trend is leading us to?

(*Professor Purchase*) Yes. It is true what you say about computer modelling, and nowadays they have methods of measuring the effects of chemicals on genes, which can screen millions of samples a month. All of that provides information into the decision making for selection of novel pharmaceutical products. It turns out that when you look historically compounds are dropped from development in what is called an attrition rate; information which you obtain early on in the development of the compound turns out not to be relevant later on. There is a big attrition in going from computer models and cells in culture to animals. There is also an attrition between going from animal studies to humans and it is only finally when you get a product on the market that you actually know exactly how well it will work.

Chairman: Lady Warnock, do you have something to ask?

Baroness Warnock: No, I was going to go on about the question of numbers but I am sure it will come up again.

Lord Hunt of Chesterton

42. Professor Banner, the Act stipulates that the committee shall have regard to (a) the effect of animal legislation on science and industry and (b) the protection of animals against avoidable suffering and unnecessary use in scientific procedures. So we have a couple of questions. How does the committee ensure that these considerations are taken into account? How do you have a balanced approach both in terms of membership and in terms of your work programme? We would be interested to hear what are the most common criticisms levelled at the committee by the science community and by the public?

(*Reverend Professor Banner*) If I could begin at the end, if I may, sir. The criticisms that are levelled I think are that, if I can put it bluntly, we are a bunch of vivisectors, that is how certain bodies would describe us, and we are a bunch of tree hugging anthropomorphic animal lovers by the other. We tend to get it in the neck both ways. The composition of the committee is a matter for the Home Secretary. I would say, though I can only comment it is not a view of the committee, that the effort over the past few years in increasing the membership has been an effort to ensure that there is wide representation of nearly all viewpoints, except those who regard violence as a legitimate means of advancing their ends. We have members who take the view that all vivisection should stop. We are criticised but I think all we can say is that by statute we are required to have certain members and that measures have been taken to ensure we have a very wide representation. In terms of the committee's programme of work, I can only say that they give the Chairman a very hard time. The proposal for the committee's work is a matter for the whole committee. It is a matter for debate in the committee what work we do. The Home Secretary can refer matters to us but the committee decides its own agenda for itself and I would suggest that balance in membership creates some balance in the sort of work we have undertaken. As regards the Act stipulating what the committee must have regard to, I am not a lawyer so I do not know whether we could, we certainly have not been subject to a judicial review. I think we would defend ourselves if we were subject to a judicial review in any case by saying that we had regard to, we had taken note of the requirements of science and industry in the sense of the requirement, if we considered an application to give further advice on it, or if we considered regulations, we would consider what the purpose was of this experimental work, whether it fitted with the Act, how serious it was and so on, whether there was a regulatory requirement and so on. We would be sensitive to those considerations whilst also sensitive to the considerations ensured by those around the table to the value of this work and the possibility for the purposes of the work being pursued in other ways.

43. Can I just ask, to do with the question of industry, presumably, as you have widened your committee in some sense, has that therefore diluted the role of industrial interest in the committee or does that remain? I just want to ask whether *vis a vis* the remarks that you made earlier this afternoon, the

Lord Hunt of Chesterton *contd.*]

role, the contribution, the influence of industry in the United Kingdom in this area is comparable with that of other countries?

(*Reverend Professor Banner*) I cannot comment, I am afraid, on the influence of industry in relation to this committee as opposed to the influence of industry on other animal welfare.

44. I meant as before in terms of enlargement and so on?

(*Reverend Professor Banner*) Forgive me, my Lord, I think you would have to do an analysis of the composition of the committee over the years and see whether the balance has changed. We are not a committee that votes very often, not because we are like the Soviet Union or some such, in previous days in that we do not have votes or if we do have votes they are decided in advance, but rather that, as I tried to say in an answer to a question earlier, members are scrupulous in trying to consider the issues in the terms set by the Act and, therefore, it is quite common for someone to say "If I had my say this application would not go forward" or alternatively "If I had my view it would go forward but under the considerations that we are asked to bring into play it should or should not as the case may be". For example, I stress a point that may not have been clear from previous answers, it is not the case that licences are given in this country for work on great apes, there is work on primates but there is no work on great apes. There are members of the committee who would say there should be no work on primates, there are members of the committee who, I imagine, might say it would be acceptable in some circumstances to work on great apes. All members of the committee, in my experience, behave scrupulously in trying to address the considerations as they are laid down in the consideration.

Lord Brennan

45. The Act supposes that your committee will seek to reach a balance between the adverse effects on the animals and the likely benefits of the research. Most of the questions so far have been directed about animals. On what evidence does your committee determine the likely benefits of research and in what depth do you consider them?

(*Reverend Professor Banner*) If I could make one preliminary comment. I should make it clear that although a good deal of interest in the committee's work relates to the few applications that we see, it is a small part of our work. What we are asking about is that particular part of our work. I would say when we consider, and if we do have an application referred to us for advice in a particular case or which we are considering in general, the terms of the applications, the application itself, the license application, will itself detail the supposed benefits or the benefits sought by the researchers in doing the experimentation. We have given further consideration to those claims through discussion and through further enquiry before giving our advice on a particular application. We have the statement made by those seeking the licences for the benefit of those they see and we may question that in the committee.

46. What sort of statement? Are we talking about a scientific presentation or a sheet of A4?

(*Reverend Professor Banner*) I think it might be helpful to your Committee, my Lord, to see a licence application.

(*Mr West*) There is a publication, *Guidance on the Operation of the Act*,[3] and one of the appendices of that has got a project licence.

(*Reverend Professor Banner*) The applicant will set out the benefits. If I could give an example without breaching any confidences. It may well be that in research into Parkinson's Disease, for example, there may be different views as to the methodologies of further research into its treatment and what one would do to, it might be primates or it might be rats. Applicants have come to the committee to give an account of their work at some length and its merits and have been questioned by members present, questions have been prepared in advance. The committee takes quite seriously when an application does come establishing the scientific merits and, therefore, the likelihood of benefits.

Lord Lucas

47. I was particularly interested by the experiment which you described in the literature you sent us. It seemed to me an exceptionally crude model chemically poisoning the brain to imitate the process of Parkinson's Disease. How did you make sure that was a useful, valid model for Parkinson's Disease? There was a lot of suffering involved in the way you have described it.

(*Reverend Professor Banner*) I would like, if I could take the opportunity, to provide you with a detailed note in answer to that question because I cannot, I am afraid, recall the details. The committee is, in relation to any application, extremely sensitive to the claims for scientific validity and if we have reached a judgment with which reasonable people disagree, I would suspect it is a judgment many reasonable people would share.

Lord Soulsby of Swaffham Prior

48. I just want to know do you find the judgments of the various ethical committees of different institutions helpful to your deliberations, both in general and in particular cases such as we are discussing?

(*Reverend Professor Banner*) The ethical review procedures?

49. Yes.

(*Reverend Professor Banner*) We are not typically privy to those discussions. When we see an application, we would see an application fresh. Neither would we be privy to the recommendation which the Animals Scientific Procedures Inspectorate may have made nor the view of ABCU. So we look at it independently. Can I add one rider,

[3] *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986.* HC 321. Appendix D gives the standard conditions for a project licence. An application form and further guidance can be found at http://www.homeoffice.gov.uk/ccpd/aps.htm

an important qualification. Members of this committee, my Lord, will be aware that many people take the view that there are no benefits from experimentation on animals because all such work is useless, for various reasons, and as part of our consideration of the cost benefit part of the legislation we are, as a preliminary to that, trying to give consideration to the question of scientific validity since that is argued in a way which is often unhelpful, either black and white. We hope as a committee we can make a contribution to a better debate by making an extended statement on that issue.

Chairman

50. If you come to some conclusions on that before we have finished our business, it would be useful to have the results transmitted to us?

(*Reverend Professor Banner*) I suspect it may be vice versa, my Lord.

Chairman: That is what I was worried about.

Lord Hunt of Chesterton

51. This is to do with statistics and, indeed, touches partly on what Lord Brennan was asking. Are you happy with the statistics on animal procedures which are currently produced? Do the statistics differentiate, as licences do, between procedures involving little or no pain and procedures involving moderate to extreme pain? What statistics would you like to see produced?

(*Reverend Professor Banner*) I cannot offer a view of the committee. We look at the statistics year on year. We have not recently, not under my chairmanship, had a prolonged discussion as to whether there is a better format for the statistics, although we have recently made particular recommendations on particular elements. I have mentioned chiefly that we have taken the view in the report on biotechnology that is coming out that there may be some merits—though there may be some difficulty in achieving it—in removing from the statistics on procedures those animals which are being bred as genetically modified but which are not genetically modified. I have not put that terribly well and one of my colleagues might help me. If large numbers of animals are bred for the purpose of modification, all the animals that are bred will count as experimental procedures which inflates the numbers, even though the majority of those animals will be ordinary unmodified animals. So we have made a recommendation that those numbers should be still counted but excluded from the number of procedures. That is one example. The other thing I would say on the question of pain, the question prompted me obviously to look at the statistics and I am astonished to find—I am sure Members of the Committee have this copy—that the details on the percentage of procedures and therefore, by inference, the number of animals which are used in mild, moderate and substantial procedures is buried on page 96 of the statistics. I would suggest that in terms of public interest and concern, the fact that by a rough estimate something like 90 per cent of animals are used in procedures which are graded as mild and moderate is a very key consideration. It is astonishing to me, I have to say now, having been encouraged to think about it, to find that rather crucial bit of information buried in an appendix to regular statistics. I think there would be considerable merit if it could be done in ensuring that the degrees of pain and the number of animals involved in each of those categories is brought more to the fore.

Earl of Onslow

52. May I ask a question. I believe for the Falklands Campaign that what they did was they anaesthetised some pigs and gave them, in effect, battlefield wounds. They shot them.

(*Reverend Professor Banner*) Yes.

53. So the surgeons could practise sewing them up.

(*Reverend Professor Banner*) Yes.

54. These pigs never recovered consciousness and consequently no pain was inflicted upon them. In my view that seems to me an absolutely totally justifiable experiment. You also have the question, and again I am searching for information, let us assume what we have is a vaccination or something which may or may not work. You think it is going to work, you inject your rat and it does not work, does that count? The rat gets the disease. I may be totally scientifically ignorant on this. I think this is the sort of question the public might want to ask. How do you codify those sorts of practices? How do you look at them? I am groping in my question.

(*Reverend Professor Banner*) On your question, of course, my Lord, you would seek further details from this from the Scientific Procedures Inspectorate. The categories are graded. The *Guidance on the Operation of the Act*, which is published by the Home Office, gives the categorisation of "mild, moderate, substantial and unclassified". If a procedure involved general anaesthesia from which an animal did not recover consciousness it would be an unclassified procedure. The "mild, moderate and substantial" are characterised in this document, my Lord, and give you an indication of the level at which a procedure is classified in terms of the sort of suffering it would cause. One point to mention is that the categorisation is given at the most severe expected level so that if in an experiment it might be expected that one out of ten animals would suffer moderate rather than mild, the experiment would be categorised as moderate. In fact, the figures which suggest moderate as 50 per cent of all procedures exaggerate the number of animals which will have suffered—if it is read incautiously—the procedures identified as moderate.

Earl of Onslow: I think I am helped. Thank you.

Chairman: We will go to the next question. Lady Nicol.

Baroness Nicol

55. At the beginning of your paragraph 17 in your paper you say the committee have, and continues to have, confidence in the professionalism of the Inspectorate. I wonder then why you feel it is necessary to have an audit of the work of the

Baroness Nicol *contd.*]

Inspectorate? Could you at the same time say whether you are satisfied that the numbers of inspectors available are sufficient and that the way that they work is agreeable to you; in that do they, for example, do unexpected visits or is everything done ahead of time? Are they always expected where they go? Could you give a general picture of how the Inspectorate works?

(*Reverend Professor Banner*) Can I comment, first of all, on the question of the audit team. It relates to one very particular aspect of the Inspectorate's work which is that when allegations are made of serious malpractice or failure to observe regulations, the Home Secretary may in those circumstances establish an investigation into that allegation. In particular, last year there was an investigation into an undercover investigation and report on Harlan-Hillcrest. The committee saw the report which was produced by the Inspectorate on that case but took the view it was not in a position to comment on the merits or otherwise of the allegations and the value of the investigation, simply because it had not been privy to the process by which the investigation had been conducted. We were not suggesting that we wish to have day to day oversight, which we could not have, of the inspectors on a day to day basis. The committee's view is that the Inspectorate is a professional, highly competent body which goes about its work vigorously and in a robust manner. However, we did think that public confidence in such investigations when they occur in future would be enhanced if the so-called independent element, which we believe the Animal Procedures Committee offers, was involved in an investigation which was, in effect, into the work of the Inspectorate. In terms of the day to day operations, again I would say obviously on those matters the Home Office and Inspectorate will wish to comment. My understanding is that, yes, visits are made at random as well as arranged. Random is not the right word, surprise visits, I think is the right phrase. Non pre-arranged visits are made by the Inspectorate.

56. Unplanned.

(*Reverend Professor Banner*) We have it as part of our agenda for this year to consider issues of enforcement and compliance and how adequate that is. We have a strong sense that we are in danger of finding ourselves in an area where there is an awful lot of anecdote and little hard evidence. There is one side of the committee which says there are so few prosecutions and so few inspectors that it cannot be that the system is well enforced, and there are others who say there are so few prosecutions that the system is working splendidly. To establish the truth of either of those, I suggest is a matter of some difficulty, though for myself, I am not taking a view of the committee, I would say that it is surprising that there are so few allegations of serious breaches and abuse given the number of experiments that go on in a year.

57. Has any member of the committee or any party from the committee ever accompanied an inspector on his examination of a body and what was the result?

(*Reverend Professor Banner*) The committee has made visits to establishments.

58. With the inspector?

(*Reverend Professor Banner*) It rather would be that the inspector comes with us on one of our visits. I have no recollection of the committee or a member of the committee accompanying an inspector but I also have no recollection of the committee asking to do that, or seeking to do it, but it may well be something to which we should give consideration.

Lord Hunt of Chesterton

59. Has the number of inspectors gone down?

(*Reverend Professor Banner*) The number of inspectors has recently gone up, my Lord. The Minister responsible in the Home Office, Mr O'Brien, recently announced, I believe, an increase in the number of inspectors—can I turn to the Secretary to help me -

(*Mr West*) From 21 to 33. That has been announced.

Lord Hunt of Chesterton: How many will there be in France, for example?

Earl of Onslow

60. Half.

(*Reverend Professor Banner*) I am afraid I could not answer the question but I suspect not as many. I could not answer the question. There is a view that unless you have an inspector standing over every procedure and a further inspector checking the inspector, there would be no confidence that the system is being rigorously applied. Therefore, I suspect that the increase will be good news to industry because it will assist in speeding up the processing of applications. It should, but I doubt in and of itself it will, reassure those who take the view that there is a lot of bad practice.

Chairman: I think we must move on.

Baroness Nicol

61. Can I just ask another question. I do think it is important. Could you give us an impression of the relationship between yourself and the Inspectorate? Do you support each other and do you agree that the success or failure of the Act itself rests on the shoulders of the Inspectorate and that, therefore, there is a need for you to work closely together? Is that acceptable?

(*Reverend Professor Banner*) I would say that we work closely together whilst maintaining a healthy and robust discussion on matters where there may be disagreement. The present chief inspector is very open in providing information where sought by the committee and the committee turns to the Inspectorate for expert advice on all sorts of matters, but that does not mean that we do not, from time to time, disagree with one another. I do take the view that the expertise of the Inspectorate is absolutely key to the operation because given the number of licences, it is not this committee and not the ABCU itself, but the inspectors on the ground day to day who have to form a view as to whether this is a good application, whether it depends upon good science, and whether it embodies good welfare as well. The

Baroness Nicol *contd.*]

expertise of the inspectors, both as scientists and with the knowledge of welfare, is crucial to the good operation of the Act. I do not know whether my colleagues would like to comment?

(*Dr Jennings*) I would just like to add two things. I think the success and failure of the Act does, in fact, depend on the Home Office Inspectorate but I think it also critically depends on the individual responsibility of everybody working under the Act. In addition there is the local Ethical Review Process (ERP) which has a responsibility to develop a culture of care and complement the work of the Home Office Inspectorate. I think we very much need these two systems operating together and I think that where the ERP works well and works well with the Inspectorate we have seen—we the RSPCA but I think also the APC in our visits—an improvement in the way the Act is implemented.

Lord Lucas

62. In the interests of speeding things up a bit perhaps you can just tell us how you are getting on on the cost benefit analysis? You hoped to have something produced before the end of 2001. Do you still believe that to be the case? Do you still think it to be a useful exercise? Can I echo something which Lord Onslow said earlier: where are you getting the basic ethics from? What underlying mechanism allows you to put a value on the particular amount of pain inflicted on a particular animal?

(*Reverend Professor Banner*) There are quite a lot of questions there. Can I begin by saying where we are. We engaged in a public consultation. The results of that in terms of a large number of submissions that came to the sub-committee, the working group, at the beginning of April, I think, or the end of March, we will be considering further. I think it will be optimistic to say we will have something produced by the end of the year but we are optimistic that something will be produced in the New Year, if you will allow that cover-all phrase. We do believe it is a useful exercise. I think the previous consultation and the previous work on the Act and its perception suggests that there is a feeling that cost benefit has been perceived by some as something of a black box. The Chief Inspector made a detailed statement on this, at some earlier stage,[4] and made it very clear that there was no sense in which this can be rendered a mathematical sum. However, what I suppose I would say is this: it is clear that at either end there is often agreement about the cost benefit. This experiment looks highly promising and involves very moderate procedures to a small number of animals. There may well be ready agreement the other way, that this seems very substantial severity to a large number of animals with very speculative benefits. In the middle there is obviously going to be disagreement. I think what we think we can contribute particularly at this stage is not an answer to that very difficult question so much as ensuring that best practice in terms of process is followed in all establishments. That is to say, I would say, that all relevant concerns in terms of what may affect the wellbeing of the animals, for example, and what may produce benefits, for example, all these relevant concerns are considered by those who have to make these judgments and consider them. I would say the best licence applications are very good in pointing to the cost to animals and the benefits and some are not so good. I think we would hope that we could contribute, at least, to improve the process and the transparency and openness of the procedure and the confidence that all relevant considerations are included in that consideration. It is never going to be a mathematical equation.

63. No. At the end of the day there has to be a balance. If you take an example I know about, mouse papers. It is legal in this country to put down mouse papers. Mice caught on these papers frequently tear limbs free and presumably hover around and die in order to prevent us from eating a bit of mouse shit which is something we have done for thousands of generations without any great problems. In deciding that mouse papers are legal, and we will inflict this cruelty on mice, we are making a value judgment. How do we help the researchers make a similar value judgment? What allows them to make that judgment?

(*Reverend Professor Banner*) It is not for the committee to take a view on mouse papers nor do we see applications day to day. You might ask the Inspectorate what view they take of mouse papers. On an issue of that kind, if an application came to us, we would ask very detailed questions about the sort of costs that were involved. We do think there is a very important part in encouraging the consciousness of what is involved in terms of the costs just because those costs can sometimes be reduced. It may well be that by improving the consideration of breadth and comprehensiveness of the considerations one assists in the reduction of something even if one does not have a refused application. I think that is very important, that the success of the Act and the better working of the Act is not a question of how many applications were refused but how the process of cost benefit, for example, encourages people to be conscious of all those costs that are involved and how they might be reduced.

Baroness Warnock

64. I want to get you to take another example, if you would. You explained an easy case where the costs are very low, the benefits are very obvious, and you explained the opposite ends of the scale. I suppose there is inevitably a matter of judgment in the middle, as you say. Have you considered the specific case of research into pain in humans, in animals as well, but certainly the nature of pain, the physiological goings on in pain where you cannot conduct research without causing pain to the animal? This always seems to me a very, very difficult case because you are almost bound to make a value judgment. If you say the benefit would be enormous, you have understood the pain in humans but in order to get this you have to put up with pain in animals along the way, is that a cost benefit?

[4] See Report of the Animal Procedures Committee for 1997, pp. 50–59.

Baroness Warnock *contd.*]

(*Reverend Professor Banner*) I have to say we have not heard that one. The regulation of the Act does not allow the licensing of any procedure which causes severe pain or distress that cannot be alleviated.

65. This would, if I can say, be autobiographical. This was the thing which caused us most difficulty on the original committee, the pain. I wondered whether you had applications to resolve that?

(*Reverend Professor Banner*) We have had applications to us which involve procedures of substantial severity, very much a minority, but on the ones which involve substantial severity I think I cannot say more than you have said which is that a good judgment is one which is sensitive to all relevant considerations and is reflective about that. I know of no answer to that.

Chairman: I would like to move on, if we may. We have got to this rather crucial question which is about alternatives. Lord Lucas.

Lord Lucas

66. In your note to the Committee, paragraph 32, you state that the Government should substantially increase its financial support for alternatives to animal testing from the £265,000 granted in 2000. From last July the Medical Research Council (MRC) has encouraged research proposals in the area of the 3Rs but has yet to receive a single application. What difficulties, other than financial ones, are there in promoting alternatives to animal experiments? What more could the APC do to promote the development and use of alternatives to animal testing?

(*Reverend Professor Banner*) Can I ask Professor Purchase to kick off on that?

(*Professor Purchase*) Certainly. I think we need to define alternatives for this discussion. The classical definition given in 1956 by Russell & Burch is now embodied as the 3Rs—Reduction, Refinement and Replacement. The trouble is that the word "alternative" creates the impression in people's mind of replacement, so when you talk about alternatives to animals you think about cell cultures or computers. In fact, it embodies also reduction in the use of animals by better experimental design and refinement by modifying the procedures that you use in the animals or, indeed, by improving the cages in which the animals are living or any of those things. It is a very broad area of consideration which most people consider only one third of. To take that just a little bit further. Alternatives in regulated procedures for safety assessment are relatively easy to get to grips with. You are talking about a limited number of toxicity studies or vaccine efficacy studies and they are common across the world. Research which aims and has proof that an alternative of one type or another is available—and there are examples of this which we could provide you with—is immediately applicable everywhere across the world and there is a great benefit from that type of investment in research. However, when you get to basic medical research, where each technique that a person develops will be novel or may be novel in relation to the problem they are studying, then alternatives become very much more an attitude of mind and a philosophy rather than they do a research programme where you can dictate exactly what might happen. Against that background what can the APC do? Well, they can support alternatives. They have a knowledge of the type of scientific work that is going on in the United Kingdom. They have a research sub-committee which decides which areas need to be researched, puts out advertisements, and evaluates the proposals. I suspect that they suffer also from partly the same problem that is identified in the question, that when one puts out an advertisement for this type of work not all the applications are of the highest quality. One then has difficulty in selecting the right applications ones and in some cases one has to go back to the applicant to get them to improve their application, so it is difficult. The other area, of course, which not the APC but the Act has introduced is that of the Ethical Review Process which is primarily about the ethical review of procedures and studies. Particularly, refinement alternatives would be a subject which can be dealt with on a local basis dealing with the local conditions and the local research that is going on. I think there is a great deal of optimism that will improve things for us.

67. Is there a list somewhere of procedures which involve either large numbers of animals or substantial pain to animals which effort should be made to find alternatives to? Is there a career path for someone who decides to research in this area? Are they going to be lecturers forever or might they become professors? If so, of what and where?

(*Reverend Professor Banner*) In relation to the second part of your comment, my Lord, I think that is a key consideration. I suspect scientific careers are not made in alternatives to research at the moment, or are rare. I think there is a sense in which it may well be that a small addition to the money will not produce a big benefit but that does not mean that a lot more money would not produce a big benefit. In other words, it may be that you cannot spend £260,000 but you could spend £2 million rather better; I do not know, it is a possibility.

Lord Brennan

68. Is there any practical problem to a levy being exacted from existing licence holders to fund research into alternatives?

(*Reverend Professor Banner*) A problem in terms of the legislation or the Treasury, I do not know, my Lord, but I would think not.

69. Practical procedures?

(*Reverend Professor Banner*) Well, there would be questions. I am sure such a proposal would be met with comments on competitiveness and so on. I suspect if one took the view of the sort of Polluter Pays type principle in relation to animals and levied something on the number of animals, it might have some effect.

70. That would be peanuts to the pharmaceutical industry?

(*Reverend Professor Banner*) Not to academics, I suspect. I am not going to take a view, my Lord, but I can assure you there would be squeals.

Lord Hunt of Chesterton

71. At a certain political party conference last year there were a lot of stands of groups who were complaining about animal use in education, experimentation and so on. The arguments given by those people manning such stands were that on the continent people are using more mechanical models; they are using many more of these computer models, and their sense was that we are all very behind in this country in not using alternatives. What I am saying is, there are those with very strong opinions for that reason.

(*Reverend Professor Banner*) Yes.

Lord Hunt of Chesterton: My question really is whether the debate—and this partly comes to the next question—is properly informed as to what the limitations are and what the possibilities are? The implication of Lord Brennan's question is—

Chairman: Can I take the opportunity for perhaps Lord Brennan to ask his question. I think it is our last most important question, if I can distinguish the various questions, before we end. Lord Brennan.

Lord Brennan

72. One of our terms of reference is to consider animal procedures having regard to public attitudes and their vulnerability in relation to that. The next Question is directed to that and I have noticed several times today, Professor Banner, you have graphically described the primitive degree of what you think to be misinformation. What is going to be the best way to ensure the public are properly informed about animal procedures?

(*Reverend Professor Banner*) I wish I knew the answer to that question, my Lord. As a committee we have taken the view that we have tried to put out more information and be more open about the way we operate. We have taken the opportunity to put our views across on the website and so on in a way which makes them more accessible and consultative. I think the key difficulty, and I think it is a matter of great regret, is that the concern for security amongst those who use animals in scientific procedures has meant that members of the public are not able to do what members of the Animal Procedures Committee are able to do, which is to go and visit establishments and see that some of the conceptions about the use of animals are misconceptions. I think it is a vicious circle that the concern about violence and so on has led to many animal establishments looking like fortresses and being fortified. I do not know how to square that circle. The fear of violence has led to concealing establishments and yet it is the openness and understanding of what is going on which I think is a key part in dispelling many of the misconceptions.

73. Your letter to the Minister[5] was a valiant but somewhat opaque attempt to get a resolution on what were obviously differences of opinion between members about the degree of openness that is reasonable. Have you had a reply and what is the progress going to be on this front?

(*Reverend Professor Banner*) There is no deep mystery here. A working party produced two reports. It differed on two rather particular points. One was how much of a licence application should be made available: all or a summary. The committee as a whole, having heard the two views, took the view that something, not the whole, should be made available but something more than a summary proposed by the majority. We are proposing to the Home Office that more information should be in the public domain from a licence application. The other dispute was about the availability of results of research which are not presently published. Those could be but would not only be negative results. There was a minority view that they should be published. The majority view of the whole committee was that there were considerable difficulties involved in making such results available. It sounds very easy but, in fact, when one starts to talk about it it is more difficult. We have made recommendations, firstly that more information should be available from the licence application and, secondly, that the Home Office should look into the mechanics of making such results available. That is a very difficult issue. We have had, I believe, no reply yet from the Home Secretary.

Earl of Onslow

74. Presumably you have come slap up against intellectual property rights and patent legislation?

(*Reverend Professor Banner*) In relation to the publication of results?

75. Yes, the publication of results.

(*Reverend Professor Banner*) Partly, yes.

76. One thing nobody wants, they have done all the work and somebody comes along and nicks it.

(*Reverend Professor Banner*) Yes. There are issues of confidentiality. There are also issues of the reliability of data which does not make it into journals or is a negative result. I am a layman, it could be explained I am sure by people around the table—my colleagues—better than me but there are considerably more difficulties than the notion that this information should just be made available.

Lord Brennan

77. There are two levels of information here. One is scientific, technical and commercial and deserves confidentiality and the other one is the ordinary member of the public's desire to know what is happening and what is it for?

(*Reverend Professor Banner*) Yes. I was distinguishing between these two issues. The project licence is one aspect where we recommend greater openness. On the matter of results, we recognise the difficulties to do with confidentiality and reliability and have referred that, because it is a difficult technical matter, to the Home Office for it to give further consideration to. It is not a matter on which the committee contains sufficient expertise to make detailed proposals for publication.

[5] Letter to Mike O'Brien from Professor Banner 3 January 2001; annex H of the Memorandum by the APC, "Events & Progress in 2000".

Lord Soulsby of Swaffham Prior

78. Just on the publication of negative results, I am interested to know where these would be published because some, as we know, have difficulty getting positive results published, let alone negative ones. Scientific and technical journals are a highly competitive business, as you know. Where would the negative results be published?

(*Reverend Professor Banner*) That is the difficulty, my Lord, yes.

(*Professor Purchase*) And how to get them peer reviewed.

Lord Soulsby of Swaffham Prior: On the web.

Chairman

79. I think time has run out on us. May I thank you, Professor Banner, Dr Jennings, and Professor Purchase. We have a number of questions that we were not able to ask. Perhaps you would reply in writing to those questions; we would be very grateful. You may also if you wish, add anything else, which I normally would have invited you to do. Had we conducted this Committee efficiently—which clearly I am not able to—we would have had the time.

(*Reverend Professor Banner*) My Lord, if you might allow me one sentence. It would be, of course, that the Animal Procedures Committee, which is a very splendid body, would be even more splendid if it had more adequate resources and an enhanced secretariat.

Chairman: Thank you so much indeed for a very informative session.

Supplementary Evidence by the Animals Procedures Committee

ANIMAL PROCEDURES COMMITTEE (APC): COMMENTS ON ORAL EVIDENCE PRESENTED ON 1 MAY 2001

The Select Committee asked for further information on a number of points. These are as follows:

REFERRAL OF APPLICATIONS TO THE APC

1. There was some doubt about whether applications sent by the Home Office to the Committee for advice are sent by statute or convention (paragraphs 6 and 7 of the transcript). Section 20(1) of the Animals (Scientific Procedures) Act 1986 states "It shall be the duty of the Animal Procedures Committee to advise the Secretary of State on such matters concerned with this Act . . . as may be referred to the Committee by the Secretary of State." Section 9(1) states "Before granting a licence . . . Under this Act the Secretary of State . . . may also consult . . . The Animal Procedures Committee . . ." From this it can be concluded that there is a *statutory* power to refer licence applications to the APC for advice, but the types referred are *by convention*. Applications currently referred to the APC include those using tobacco as a causative agent in the study of disease; microsurgical training; the use of non-human primates in procedures of substantial severity: the use of wild caught non-human primates; and the testing of cosmetics.

MORAL AUTHORITY OF THE APC

2. There were references to the moral authority by which the APC operated (paragraphs 8 to 12, and 62 of the transcript). As the Chairman of the APC stated, the Committee has a statutory authority. It could be said that any moral authority of the APC derives from the qualifications, background and experience of its members.

DEFINITION OF WELFARE

3. Various definitions of welfare are available in scientific literature. One, quoted in Appleby and Hughes, which the Select Committee might find helpful is:

> "The state of wellbeing brought about by meeting the physical, environmental, nutritional, behavioural and social needs of the animal or groups of animals under the care, supervision or influence of people."

PARKINSON'S DISEASE EXPERIMENT

4. There was a reference at Question 47 of the transcript to an experiment into Parkinson's disease. This possibly refers to the section of the APC's report for 1999 (paragraphs 36 to 52) entitled "Use of Primates in research on Parkinson's disease". I attach a paper containing extracts from the minutes of the meetings of the APC in 1999 where applications involving the use of primates in research into Parkinson's disease were discussed. [*Not printed*].

FORTHCOMING REPORTS BY THE APC

5. We were asked to provide the Select Committee with the APC's conclusions about the validity of animal experimentation (Question 50 of the transcript). That will be a part of the Committee's report on the Cost/ Benefit assessment, which we are hoping to conclude by the end of the year. Both that report (and those on Biotechnology and Openness, whose publication is imminent) will be supplied to the Select Committee.

MEMBERS OF THE APC ACCOMPANYING INSPECTORS ON VISITS TO ESTABLISHMENTS

6. At Question 58 of the transcript the Chairman said that the APC might consider asking if members could accompany Inspectors on their visits to establishments carrying out scientific procedures under the Animal (Scientific Procedures) Act. The Select Committee will wish to be aware that only Animal (Scientific Procedures) Inspectors (and police with a warrant) have the power to enter such establishments. It follows that in order for a member of the APC to accompany an Inspector on a visit the permission of the establishment involved would have previously to have been obtained.

EXPERIMENTS INVOLVING CHIMPANZEES; AND THE USE OF "MOUSE PAPERS"

7. During the course of the APC's oral evidence there were references to particular controversial procedures and practices. First, it may be helpful to the Select Committee's consideration to state that the Home Secretary decided in 1997 that licences will not be issued for programmes of work involving the use of chimpanzees or any other Great Ape species—pygmy chimpanzees, gorillas and orang utans.

8. Secondly, there was also a reference to the use of mouse papers for vermin control. Such a practice is not a scientific procedure controlled by the Animal (Scientific Procedures) Act. The use of mouse papers is a good example of the different standards applied to animals under the control of the Animals (Scientific Procedures) Act 1986 compared with those not under that Act's control. Under the Act the Secretary of State cannot license any procedure likely to cause severe pain or distress that cannot be alleviated.

RESEARCH RECOMMENDED BY THE APC

9. There was a reference in Question 67 of the transcript to the desirability of focussing research to those areas using the most numbers of animals and/or those involving the highest levels of severity. The great majority of the research grants funded by the Home Office at the APC's recommendation have been aimed at achieving one or more of the "Three Rs":

— Reduction in the numbers of animals used;

— Replacement of animals by non-animal means, such as cell cultures; and

— Refinement of procedures to minimise pain or distress.

10. In assessing the relative merits of competing research proposals the Research and Alternatives sub-committee of the APC gives particular attention to the practical benefits to animal welfare which will accrue from the research. Many of the applications for awards have been successful because of their possible benefits in alleviating pain and, other things being equal, the more severe the pain to be relieved, the more favourable would be the assessment. The great majority of the research proposals which we have supported have been on mice. There are several reasons for this: mice are the main species on which toxicological studies are carried out; toxicological studies can be routine, repetitive and inimical to welfare; and it is such procedures which appear to be the most susceptible to modification under one or more of the "three Rs".

11. In summary, therefore, we can say that the research funding that the APC has recommended has focussed on the species most frequently used in animal experimentation and on the most painful procedures. Although this is not a stated policy, it is the almost inevitable outcome of seeking proposals in furtherance of the "three Rs".

EDUCATION AND TRAINING

12. The Education and Training sub-committee of the APC estimated that the cost of the proposed syllabus would be between £1,000 and £2,000. That would include the cost of trainers, accommodation and equipment and the cost of the salary of the trainee. In establishments which are already working to best practice, the proposed course will formalise current standards; it will introduce new standards in other establishments.

13. REGULATION AND ITS EFFECT ON THE EXPORT OF ANIMAL USE

We take this issue seriously. It is in nobody's interest for there to be ineffective regulation, which will increase bureaucracy with little benefit to animal welfare or the three Rs. Firm evidence of the effect of regulation on the export of animal use is difficult to find, and so therefore is any analysis of the balance referred to. However, we are aware of the work done by the Pharmaceutical Industries' Competitiveness Task

Force (PICTIF) and Professor Purchase's expert group on regulation (mentioned at Question 16 of the transcript of our evidence).

When the Committee discusses new regulations members whose background makes them sensitive to these concerns would ensure that this issue is considered. There is a fine balance to be struck between the extent of restriction in the UK, the export of work, and the possible effect on work in other countries. Over and above that there is the general desirability of reducing bureaucracy, but only where there would be no compromise on welfare standards.

Future Need for Animals

15. There is an increase in the use of GM animals and this trend can be identified in current Home Office statistics. Although the overall numbers of scientific procedures on animals have been declining, those on both naturally occurring mutants and GM animals have been increasing.

THOUSANDS OF SCIENTIFIC PROCEDURES (PERCENTAGE OF 1992)

	1992	*1995*	*1998*	*1999*
Normal Animals	2,681	2,268	1,953	1,894
	(100%)	(85%)	(73%)	(71%)
Animals with a harmful genetic defect (mutants)	174	227	259	251
	(100%)	(130%)	(149%)	(144%)
Genetically modified animals	74	215	448	512
	(100%)	(291%)	(605%)	(692%)
All Animals	2,930	2,710	2,660	2,657
	(100%)	(92%)	(91%)	(90%)

It is expected that this will lead to an overall increase, perhaps a marked increase, in overall animal use. There may possibly come a point at which no further animal procedures can be justified under the cost/benefit system, but any proposal would need to be assessed on an individual basis.

Future Programme of the APC

16. Our review of the Act, carried out in 1997 identified the areas which needed most examination and we have made progress in addressing them. Our work programme (annex D of the note by the Secretariat) identifies topics that we wish to examine further, for example enforcement and compliance; and the accommodation and care of animals. The identification of other areas in need of reform will stem from our general work.

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